K051219

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JUN 29 2005

IX. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

ARTHREX PUSHLOCK™

MANUFACTURER / SPONSOR	Arthrex, Inc. 1370 Creekside Boulevard Naples, Florida 34108-1945
510(K) CONTACT:	Sally Foust, RAC Sr. Regulatory Affairs Specialist Telephone: (239) 643-5553 ext. 1251 FAX: (239) 598-5539
TRADE NAME:	PushLock™
COMMON NAME:	Fastener; Screw, Fixation, Bone
PRODUCT CODE / CLASSIFICATION NAME	HWC/MBI 21 CFR 888.3040 Fastener, Fixation, Nondegradable, Soft Tissue Smooth or threaded metallic bone fixation fastener MAI/ 21 CFR 888.3030 Fastener, Fixation, Biodegradable, Soft Tissue

PREDICATE DEVICE:
Bio-FASTak Suture Anchors: K971723 & K000506

DEVICE DESCRIPTION AND INTENDED USE:
The Arthrex PushLock™ (suture anchor) is a 2 piece "push-in" anchor. The suture anchor is designed to use the principles of compression to force the eyelet, threaded with appropriate suture, into a predrilled hole.

The Arthrex PushLock™ is intended for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and pelvis.

SUBSTANTIAL EQUIVALENCE SUMMARY
The Arthrex PushLock™ (suture anchor) is substantially equivalent to the predicate Arthrex Bio-FASTak Suture Anchor in which the basic features and intended uses are the same. Any differences between the PushLock™ (suture anchor) and the predicate Bio-FASTak Anchor are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the new PushLock™ (suture anchor) is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2005

Ms. Sally Foust, RAC
Senior Regulatory Affairs Specialist
Arthrex Incorporated
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K051219
Trade/Device Name: Arthrex PushLock™
Regulation Number: 21 CFR 888.3040, 888.3030
Regulation Name: Smooth or threaded metallic bone fixation fastener, Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI, MBI, HWC
Dated: June 10, 2005
Received: June 13, 2005

Dear Ms. Foust:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. INDICATIONS FOR USE FORM

510(k) Number (if known): K051219

Device Name: Arthrex PushLock™

Indications for Use:

The Arthrex PushLock™ is intended for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and pelvis in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction

Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051219